A patient’s guide to Collagenase SANTYL® Ointment
What is Collagenase SANTYL® Ointment?

SANTYL® Ointment is an FDA-approved prescription ointment that cleans wounds, promoting an optimal environment for them to heal.

Physicians have prescribed SANTYL® Ointment for more than 20 years to help clear out many types of wounds, including chronic dermal ulcers (such as pressure ulcers, diabetic ulcers, and venous ulcers) and severely burned areas.

How does Collagenase SANTYL® Ointment work?

Out with unhealthy tissue, in with a healthy environment for healing

SANTYL® Ointment helps clean your wound by removing nonliving tissue, and not harming healthy tissue. Removing nonliving tissue can allow new, healthy tissue to form.

You are encouraged to report negative side effects of prescription drugs to the FDA. Call 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see enclosed complete prescribing information.
What should I know about Collagenase SANTYL® Ointment?

Always use the fully prescribed amount of SANTYL® Ointment as instructed by your healthcare professional

Your healthcare professional will show you how much SANTYL® Ointment your wound needs and how to apply it. SANTYL® Ointment should always be evenly applied to the wound. If you evenly apply the precise amount prescribed by your healthcare professional and use all the ointment appropriately filled in your cup, it should be about “nickel-deep” (the depth of a nickel lying flat).

Potential treatment effects, though rare, may occur while using SANTYL® Ointment

A small number of patients may experience temporary redness when they apply the ointment, especially if the medicine comes into contact with tissue surrounding the wound. If a large amount of fluid or wound material builds up, you may experience irritation. If this happens, talk to your healthcare professional. He or she may tell you to change your wound dressing more frequently until the amount of wound material or drainage decreases.

Do not refrigerate SANTYL® Ointment or expose it to high levels of heat

Store SANTYL® Ointment at room temperature (no higher than 25° C or 77° F).

Do not use SANTYL® Ointment if you are allergic to collagenase or if it has not been prescribed to you

If you are allergic or sensitive to collagenase or any other ingredients of SANTYL® Ointment, you should not use the product. It is important to use SANTYL® Ointment only as prescribed, and never share with another person.

Keep SANTYL® Ointment out of the reach of children.
For best results, always use the correct amount of ointment.

Fill your medicine cup with the correct amount of Collagenase SANTYL® Ointment directed by your healthcare professional. Use all the SANTYL® Ointment in your cup.

On follow-up visits, your healthcare professional may update the amount of SANTYL® Ointment required to treat your wound.
How do I appropriately apply Collagenase SANTYL® Ointment?

3 simple steps to proper application

1. RINSE
   RINSE your wound with saline solution and pat dry with gauze

2. APPLY
   APPLY the correct amount of SANTYL® Ointment from your medicine cup using an applicator

3. DRESS
   DRESS your wound with a fresh bandage or gauze as instructed by your healthcare professional

Do not use dressings containing silver (Ag) or iodine ($I_2$) with SANTYL® Ointment, as these ions inactivate collagenase, the active enzyme in SANTYL® Ointment.
Call your pharmacy to make sure your prescription is available

SANTYL® Ointment is covered by all Medicare Part D plans.

Visit www.santyl.com for more information.

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Occasional slight temporary redness has been noted in surrounding tissue when applied outside the wound. One case of an allergic reaction has been reported after 1 year of treatment with collagenase and a steroid cream. Use of Collagenase SANTYL® Ointment should be stopped when debridement is complete and granulation tissue is well established.
DESCRIPTION: Collagenase SANTYL® Ointment is a sterile enzymatic debriding ointment which contains 250 collagenase units per gram of white petrolatum USP. The enzyme collagenase is derived from the fermentation by Clostridium histolyticum. It possesses the unique ability to digest collagen in necrotic tissue.

CLINICAL PHARMACOLOGY: Since collagen accounts for 75% of the dry weight of skin tissue, the ability of collagenase to digest collagen in the physiological pH and temperature range makes it particularly effective in the removal of detritus. Collagenase thus contributes towards the formation of granulation tissue and subsequent epithelization of dermal ulcers and severely burned areas. Collagen in healthy tissue or in newly formed granulation tissue is not attacked. There is no information available on collagenase absorption through skin or its concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, degree of uptake by a particular organ or in the fetus, and passage across the blood brain barrier.

INDICATIONS AND USAGE: Collagenase SANTYL® Ointment is indicated for debriding chronic dermal ulcers and severely burned areas. The combination of collagenase and cortisone has been reported. Safety and effectiveness in pediatric patients have not been established. Therapy with Collagenase SANTYL® Ointment should be discontinued until remission of the infection. The antibiotic should be applied to the wound prior to the application of Collagenase SANTYL® Ointment. Should the infection not respond, therapy with Collagenase SANTYL® Ointment should be discontinued until remission of the infection.

CONTRAINDICATIONS: Collagenase SANTYL® Ointment is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase.

PRECAUTIONS: The optimal pH range of collagenase is 6 to 8. Higher or lower pH conditions will decrease the enzyme’s activity and appropriate precautions should be taken. The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury and silver which are used in some antiseptics. When it is suspected such materials have been used, the site should be carefully cleansed by repeated washings with normal saline solution before Collagenase SANTYL® Ointment is applied. Soaks containing metal ions or acidic solutions should be avoided because of the metal ion and low pH. Cleansing materials such as Dakin’s solution and normal saline are compatible with Collagenase SANTYL® Ointment.

Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia. A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when Collagenase SANTYL® Ointment was not confined to the wound. Therefore, the ointment should be applied carefully within the area of the wound. Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS: No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. However, one case of systemic manifestations of hypersensitivity to collagenase in a patient treated for more than one year with a sterile gauze pad which is then applied to the wound and properly secured.

OVERdosage: No systemic or local reaction attributed to overdose has been observed in clinical investigations and clinical use. If deemed necessary the enzyme may be inactivated by washing the area with povidone iodine.

DOSEAGE AND ADMINISTRATION: Collagenase SANTYL® Ointment should be applied once daily (or more frequently if the dressing becomes soiled, as from incontinence). When clinically indicated, crosshatching thick eschar with a #10 blade allows Collagenase SANTYL® Ointment more surface contact with necrotic debris. It is also desirable to remove, with forceps and scissors, as much loosened detritus as can be done readily. Use Collagenase SANTYL® Ointment in the following manner:

- Prior to application the wound should be cleansed of debris and digested material by gently rubbing with a gauze pad saturated with normal saline solution, or with the desired cleansing agent compatible with Collagenase SANTYL® Ointment (See PRECAUTIONS), followed by a normal saline solution rinse.
- Whenever infection is present, it is desirable to use an appropriate topical antibiotic powder. The antibiotic should be applied to the wound prior to the application of Collagenase SANTYL® Ointment. Should the infection not respond, therapy with Collagenase SANTYL® Ointment should be discontinued until remission of the infection.

HOW SUPPLIED: Collagenase SANTYL® Ointment contains 250 units of collagenase enzyme per gram of white petrolatum USP.

Do not store above 25°C (77°F). Sterility guaranteed until tube is opened.


Manufactured by Healthpoint, Ltd.
Fort Worth, Texas 76107
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Reorder Nos.
0064-5010-15 (15 g tube)
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